STATEMENT BY

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Introduction

Mr. Chairman and Members of the Committee, I am Dr. William Egan, Acting Director, Office of Vaccines Research and Review (OVRR), of the Food and Drug Administration's (FDA or the Agency) Center for Biologics Evaluation and Research (CBER). CBER's Office of Vaccines Research and Review is responsible for the regulation and oversight of vaccines in the United States. On behalf of FDA, I appreciate the opportunity to participate in this hearing as the Committee explores the hypothesized link between thimerosal in vaccines and autism. I want to assure the Committee, the public and, the parents who are here today, that FDA takes their concerns very seriously. I will take this opportunity to explain FDA's ongoing efforts to ensure that vaccines in the U.S. are safe and effective.

As you know, vaccines have contributed to a significant reduction in many childhood diseases such as diphtheria, polio, measles, and whooping cough. It is now rare for American children to experience the devastating effects of these illnesses and infant deaths due to these diseases have essentially disappeared in countries with high vaccination coverage, such as the U.S. As a recent example, prior to the introduction of a vaccine in 1985, an estimated 20,000 cases of invasive *Haemophilus influenzae* type b (Hib) disease, primarily meningitis, occurred each year in the U.S. Now, because of widespread vaccination, the number of cases of invasive Hib disease has decreased by more than 98 percent; in the U.S., Hib disease was the leading cause of acquired mental retardation. Although vaccines have contributed greatly to the

health and well being of our children, we must nonetheless be vigilant of any potential safety concern related to vaccines.

Thimerosal Reduction in Vaccines

In response to Section 413 of the Food and Drug Administration Modernization Act (FDAMA) of 1997, FDA conducted a review of, inter alia, the use of thimerosal in childhood vaccines. This review led to the realization that some children, during their first 6 months of life, might receive amounts of ethylmercury, from the preservative, thimerosal, in excess of the Environmental Protection Agency's guidelines for methylmercury, although not the Agency for Toxic Substances and Disease Registry or FDA guidelines. Although there were no known risks from these levels of thimerosal in vaccines, the Public Health Service, along with the American Academy of Pediatrics and the American Academy of Family Physicians felt that it was prudent to reduce childhood exposure to mercury from all sources, including vaccines, as feasible.

Consistent with this goal, FDA has encouraged and worked with manufacturers to develop new vaccines and new vaccine formulations that are either thimerosal-free or contain only trace amounts of thimerosal as a preservative.

We are pleased to report that FDA actions have resulted in a marked reduction in thimerosal exposure from vaccines. At this time, with the exception of the influenza vaccine – and I will address this vaccine in a moment, all of the routinely recommended licensed pediatric

vaccines (DTaP, Hepatitis B, pneumococcal conjugate, IPV, MMR, and varicella) that are currently manufactured for the U.S. market are either thimerosal-free or contain only trace amounts of thimerosal. As just noted, the exception is the inactivated influenza virus vaccine that has only recently been recommended for routine use in a pediatric population, 6 months through 23 months of age. FDA approved two preservative-free formulations of the injectable influenza vaccine containing only a trace of mercury from thimerosal. One of these formulations is approved for use in the pediatric population. The two licensed manufacturers of the injectable influenzae vaccine also market their product in a thimerosal preservative-containing formulation.

The reduction or elimination of thimerosal was, in principle, achievable because over time it was possible to replace multi-dose vials with single dose vials, which do not require a preservative.

Prior to this initiative to reduce or eliminate thimerosal from childhood vaccines, the maximum cumulative exposure to mercury as ethylmercury via routine childhood vaccinations during the first 6 months of life was approximately 187.5 micrograms. The vaccines with trace amount of thimerosal licensed to date contain less than 1 microgram of mercury per dose. With the newly formulated vaccines, the maximum cumulative exposure during the first 6 months of life is less than three micrograms of mercury. This use of vaccines with no or only trace amounts of thimerosal represents a greater than 98 percent reduction from previous maximum exposure in young infants. A table listing vaccines,

preservative contents and manufactures and can be found on FDA's website: *www.fda.gov/cber/vaccine/thimerosal.htm*. Although not administered to children below the age of 6 months, the influenza vaccine could add an additional 25 micrograms of mercury during the first year of life, if each of the two doses contains thimerosal as a preservative. Since FDA last appeared before the Committee to discuss this issue, we have approved the following vaccines that are either thimerosal-free or contain only a trace amount of thimerosal:

- Pediarix: Diphtheria & Tetanus Toxoids & Acellurlar Pertussis Vaccine Adsorbed, Hepatitis B and Inactivated Poliovirus Vaccine Combined manufactured by GlaxoSmithKline Biologics.
- DECAVAC: Tetanus and Diphtheria Toxoids Adsorbed (Td), for adult use manufactured by Aventis Pasteur, Inc.
- Diphtheria and Tetanus Toxoids Adsorbed (DT), for pediatric use, manufactured by Aventis Pasteur, Inc.
- Tetanus and Diphtheria Toxoids Adsorbed (Td) for adult use, manufactured by Aventis Pasteur Ltd.

In addition, a live-attenuated influenza vaccine that is thimerosal free, FluMist, manufactured by MedImmune, was licensed in 2003 for those 5-49 years of age.

Institute of Medicine (IOM) Review

The Immunization Safety Review Committee of the Institute of Medicine (IOM) completed two reviews of studies addressing a potential link between thimerosal containing vaccines and

autism that are relevant to this hearing today. The first IOM review was conducted in 2001. In 2001, based on the data then available, the IOM concluded that the body of data was inadequate to either accept or reject a causal relationship between thimerosal-containing vaccines and neurodevelopmental disorders, including autism. The Committee, prompted by the accumulation of considerable new data, re-reviewed this issue of a potential causal relationship between thimerosal-containing vaccines and autism in 2004. Based on a review of this full body of data, which included epidemiological studies from the United States, Denmark, Sweden, and the United Kingdom, the Committee concluded: "Thus, based on this body of evidence, the committee concludes that the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism."

Conclusion

FDA has succeeded in reducing children's exposure to mercury from vaccines during the first 6 months of life and continues to work toward reducing everyone's thimerosal exposure through vaccines. With the exception of the inactivated influenza vaccine, which just this year was added to the list of routinely recommended pediatric vaccines, all routinely recommended licensed pediatric vaccines that are currently being manufactured for the U.S. market contain no thimerosal or only trace amounts of thimerosal. FDA, together with our colleagues within the other Health and Human Service agencies, will continue to study data relating to the incidence and etiology of autism.

I would be happy to respond to any questions.

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